REMARKS

After entry of this amendment, claims 1, 3-18, 20-25 are pending, of which claims 4-6, 16-18, 20, and 21 are withdrawn. The claims have been amended without prejudice or disclaimer and find support *inter alia* in the original claims. The amendments to claims 1 and 16 find further support in the specification, for example, at page 23, lines 22-28. The amendments to claims 12 and 13 find support in original claim 13 and additionally in the specification, for example, at page 38, lines 2-3, 20-21. Claims 3, 5-6, 13-14, 22-23 have been amended without prejudice or disclaimer for proper antecedent basis. No new matter has been added.

In the event that claim 1 is found allowable, then rejoinder of the non-elected subject matter that depends from or otherwise includes all the limitations of the allowed claim is respectfully requested. MPEP § 821.04(b).

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claim 1, 3, 7-9, 11-15, and 22-25 for indefiniteness for the recitation of the term "substantially." Applicants respectfully disagree; however, in order to expedite prosecution, the claims have been amended without prejudice or disclaimer. In light of the amendment, the rejection is believed to be rendered moot. Withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 112, first paragraph

Written Description Rejection

The Examiner rejected claims 1, 7-15, and 22-25 under 35 U.S.C. § 112, first paragraph, for allegedly failing to comply with the written description requirement. Applicants strongly disagree and traverse the rejection for the reasons already of record and the following additional reasons.

"The burden of showing that the claimed invention is not described in the application rests on the PTO in the first instance." *In re Edwards,* 568 F.2d 1349, 1354 (CCPA 1978); Ex *parte Heck*, Appeal 2008-2875 (BPAI 2008). A description as filed is presumed to be adequate, unless or until sufficient evidence or reasoning to the contrary has been presented by the examiner to rebut the presumption. See, e.g., *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971).

The "written description" requirement under 35 U.S.C. § 112, first paragraph, serves both to satisfy the inventor's obligation to disclose the technologic knowledge upon which the patent is based, and to demonstrate that the patentee was in possession of the invention that is claimed. *Capon v. Eshhar*, 418 F.3d 1349, 1357, 76 USPQ2d 1078, 1084 (Fed. Cir. 2005); *see also* MPEP § 2163. Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. *See* MPEP § 2163 (citation omitted).

A written description of an invention involving a nucleic acid, like a description of a chemical genus, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). For a claimed genus, the written description requirement may be satisfied through sufficient description of a representative number of species by actual reduction to practice, by disclosure of relevant identifying characteristics, by functional characteristics coupled with known or disclosed correlation between function and structure, or by a combination of such identifying characteristics. *See Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997). However, the determination of what is required to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter. *Capon v. Eshhar*, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

The Examiner alleges that the specification has not described any functional equivalents homologs of SEQ ID NO: 1, any nucleic acids with 98% identity to SEQ ID NO: 1, other nucleic acids of SEQ ID NO: 1, or any expression pattern for the promoter of bases 300 to 583 of SEQ ID NO: 1. The Examiner further alleges that the specification does not describe the necessary elements essential for promoter activity. The Examiner further contends that the genus of nucleic acid sequences encompassed by the claims is very large and may encompass over 4^{17} molecules concluding that the written description has not been met for the genus of nucleic acids with promoter activity equivalent to SEQ ID NO: 1 that comprise nucleotide sequences with

98% identity to SEQ ID NO: 1 as claimed. Applicants strongly disagree and request reconsideration, especially in light of the recent Board of Patent Appeals and Interference decision of *Ex parte Heck*, Appeal 2008-2875 (BPAI 2008) (a copy is attached for the Examiner's convenience).

Analogous to *Ex parte Heck*, the present specification explicitly teaches the structure of promoter sequences by providing the nucleic acid of SEQ ID NO: 1 and the skilled artisan would thus know the structure, *i.e.* at least 98% identity to SEQ ID NO: 1. As in *Ex parte Heck*, while the claims relate to fragments of SEQ ID NO: 1 and to sequences having at least 98% identity with SEQ ID NO: 1, the Board agreed with appellants that "these groups define a subset of sequences fully described by SEQ ID NO: 1." The Board further held that the structure of the claimed fragment was provided and thus described. The Board in reversing the written description rejection held that the same analysis applied to sequences having at least 98% identity to SEQ ID NO: 1, where the Board found that "the skilled artisan would know the structure, i.e. at least 98% identity to SEQ ID NO: 1, as well as function, having promoter activity." (*Ex parte Heck*, see page 7-8 of attached copy). Thus, analogous to the holding in *Ex parte Heck*, fragments and sequences with 98% identity to SEQ ID NO: 1 as claimed are fully described in the present specification.

The Examiner in response to our previous arguments regarding motifs alleges that the arguments provide another example of unpredictability of tissue specific promoters and unpredictability of which motifs, domains, or subsequences are responsible for a particular expression pattern. Applicants respectfully disagree with the Examiner's interpretation. Whether a promoter is a constitutive promoter or a tissue-specific promoter, the motifs and the domains described and provided in the present specification, for example in the tables of Examples 14-15 at pages 59-60, describe to one of skill in the art the identity of which regions would likely be important to promoter function and where and where not to modify the sequence. The specification has thus clearly disclosed relevant identifying characteristics providing sufficient description under the *Lilly* standard. *Regents of the University of California v. Eli Lilly and Co.*, 119 F.3d at 1568 (For a claimed genus, the written description requirement may be satisfied . . . by disclosure of relevant identifying characteristics . . .).

Moreover, similar to the specification at issue in *Ex parte Heck*, the present specification describes the creation of variants of SEQ ID NO: 1 and describes known methods for

construction of promoter fragments and variants, see for example pages 25-30. The Examiner is reminded that written description is reviewed from the standpoint of one of skill in the art at the time the application is filed. *Wang Labs. v. Toshiba Corp.*, 993 F.2d 858, 865, (Fed. Cir. 1993). Fragments and sequences having 98% identity to a particular sequence can be generated by one of skill in the art by routine methods. Furthermore, as of the filing date, it is well known that substantial alterations can be made to a promoter sequence while retaining promoter function, as shown, for example, in the references cited by the Examiner under the enablement rejection. Further, promoter activity can be routinely confirmed by expression assays, for example, using the constructs prepared according to Examples 3 and 4 of the present specification and the assays according to Example 6. These same assays are applicable whether the promoter is a constitutive promoter or a tissue-specific promoter, i.e. one of skill in the art would evaluate in which tissue the gene of interest is expressed to determine its expression pattern. For example, if expressed in all tissues, it would then be considered a constitutive promoter, or if expressed preferentially in certain tissues, it would be considered a tissue specific promoter. Thus, the present specification describes the preparation of derivatives of full-length promoter sequences, as well as methods of determining activity of such promoter sequences. Additionally, the specification exemplifies promoter function in three different plant species.

The Examiner also alleges that the specification does not describe expression patterns for transformed maize past the T_0 plantlet stage. Regardless of whether the activity has been shown at the plantlet stage or in further generations, the specification has nonetheless demonstrated in working examples the claimed promoter activity in three different plant species or at the very least in at least two different plant species. See *In re Angstadt*, 537 F.2d 498 (CCPA 1976) (holding that there has never been a requirement that every species encompassed by a claim must be disclosed or exemplified in a working example).

Therefore, one of ordinary skill in the art could readily identify promoter fragments and variants with a preserved promoter activity from a promoter sequence and a description of its promoter activity by using routine experimentation as described in the present application or known in the art at the time of filing. Because the existing knowledge and content of the art is such that one skilled artisan could readily envision fragments and variants having 98% identity to the disclosed sequences from the present specification, the written description requirement is satisfied. This is also consistent with the Board's finding in *Ex parte Heck*, where the written

description requirement was found to be satisfied for a claim reciting a genus to polynucleotide sequences having at least 98% identity to the single disclosed sequence because "the skilled artisan would know the structure, i.e. at least 98% identity to SEQ ID NO: 1, as well as the function, having promoter activity." *See Ex parte Heck*, at page 8 of the attached copy.

The Examiner additionally rejected claim 1 for allegedly containing new matter. Applicants respectfully disagree. The specification clearly provides support for the statement quoted by the Examiner, for example, at page 22, line 21, which Applicants had indicated in the last response. Nonetheless, the claim has been amended without disclaimer or prejudice. The rejection is believed to be rendered moot.

For at least the above reasons, reconsideration and withdrawal of the rejection is respectfully requested.

Enablement Rejection

The Examiner rejected claims 1, 3, 7-15, and 22-25 under 35 U.S.C. § 112, first paragraph, for allegedly lacking an enabling disclosure. Applicants traverse the rejection.

The Examiner alleges that the specification is enabling for a promoter comprising a fragment of SEQ ID NO: 1, but not equivalents or variants thereof. The Examiner further argues that the art is so unpredictable as to mak any homologs or variants that retain promoter activity of SEQ ID NO: 1 non-enabled, citing various references. Additionally, the Examiner notes that the promoter causes different expression patterns in different plants. Applicants strongly disagree for the reasons already of record and for the following additional reasons that the claims as amended are not enabled.

The Examiner alleges that the specification does not provide guidance for any sequence variants of SEQ ID NO: 1. The Examiner alleges that internal deletions, substitutions and insertions within a promoter are unpredictable, citing Donald *et al.* (hereinafter "Donald"). The Examiner further alleges that the region of a given promoter with a specific activity cannot be predicted and involves complex interaction of different subdomains, citing Benfey *et al.* (hereinafter "Benfey"). Additionally, the Examiner cites Kim *et al.* (hereinafter "Kim") to support the position that even a small region may be critical for activity and such criticality must be determined empirically. Applicants strongly disagree with the Examiner's characterization of

these references, especially in light of the recent Board of Patent Appeals and Interference decision of *Ex parte Heck*, Appeal 2008-2875 (BPAI 2008) (see attached copy).

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application." *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993). "[T]o be enabling, the specification ... must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'" *Id.* at 1561, *quoted in Genentech, Inc. v. Novo Nordisk A/S,* 108 F.3d 1361, 1365 (Fed. Cir. 1997). Thus, "there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and use the invention as broadly as it is claimed." *In re Vaeck*, 947 F.2d 488, 496 & n. 23 (Fed. Cir. 1991), *quoted in Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 (Fed. Cir. 1999). Some experimentation, even a considerable amount, is not "undue" if, e.g., it is merely routine, or if the specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

Contrary to the Examiner's assertion, the Board in *Ex parte Heck* when reviewing at least two of the very references cited herein by the Examiner, *i.e.* Donald and Kim, rather found that these references demonstrate "the routine nature of promoter analysis, since both Donald and Kim use standard methods to determine which sequence elements affect promoter strength and which elements have no impact." *Ex parte Heck*, Appeal 2008-2875 (BPAI 2008). Furthermore the Board in *Ex parte Heck* agreed with appellants "that it is well within the level of ordinary skill in the art to prepare nucleic acid sequences that are 98% identical to SEQ ID NO: 1." *Id.* Moreover, analogous to the specification at issue in *Ex parte Heck*, the present specification also "teaches the preparation of derivatives of full length promoter sequences, as well as methods of determining activity of such promoter sequences." Additionally, the present specification exemplifies promoter function in three different plant species.

The Examiner also contends that the experiments in Kim "do not provide any information about the ptxA promoter of the instant SEQ ID NO: 1" and that "the elements of the 35 S promoter [of Benfey] do not provide guidance that is relevant to the elements of the ptxA promoter of the instant invention." (Office Action, page 18). Accordingly, because Kim and

Benfey are not relevant to the present promoter as acknowledged by the Examiner, these references are not relevant to this rejection and should not even be applied in this rejection.

Contrary to the Examiner's conclusions and analogous to *Ex parte Heck*, all three references cited by the Examiner rather show that promoter fragments with a particular activity can be identified by standard deletion experiments, that essential sequence elements can be predicted and identified by sequence analysis, and that those sequence elements represent only a minor part of the promoter sequence. By showing which parts of the promoter sequence are essential through routine experimentation and that only small parts of the original promoter sequence are necessary for activity, Donald, Kim, and Benfey demonstrate that it is readily within the skill of the art to determine which parts of a promoter sequence can be changed, which substitutions can (or cannot) be made which will affect activity. A skilled artisan would recognize most of a promoter sequence might be changed without losing promoter activity. Thus, from a promoter sequence and a description of its promoter activity, a person of skill in the art can readily identify promoter fragments and variants with a preserved promoter activity and the important sequence elements contained therein by using routine experimentation as described in the present application and as demonstrated by Kim, Donald, and Benfey. Furthermore, one of ordinary skill in the art can readily identify the majority of nucleotides in the promoter sequence which are not necessary for activity and which might be changed or deleted without losing the promoter activity. By using routine experimentation, a skilled artisan would be readily able to construct sequence fragments and variants preserving the claimed promoter activity. Accordingly, consistent with the Board's finding in *Ex parte Heck*, the specification should be likewise found enabling for the present claims.

In addition, the Examiner again cites to the thesis by David Phillip Bown (hereinafter "Bown") for allegedly teaching that the tissue specificity is unpredictable and is species-dependent concluding that claims to particular tissue specificity are enabled only for the plants in which a tissue-specificity has been determined (Office Action, page 14). Applicants strongly disagree with the Examiner's characterization of Bown and conclusions.

The Examiner did not find persuasive that the expression of an isolated promoter sequence is different than the expression of a naturally occurring endogenous gene. The Examiner alleges that this is because the instant claims do not limit the genomic environment of the locus for the nucleic acid being claimed or the sequence of the mRNA transcribed.

Applicants respectfully disagree and strongly urge reconsideration and withdrawal of the rejection for the reasons of record and for the following additional reasons.

First, the claims clearly recite that the promoter is heterologous with respect to the gene of interest.

Moreover, it is well known in the art that the activity of an isolated promoter is not always identical with the expression of a naturally occurring endogenous gene in a particular tissue. For example, Sieburth *et al.* (hereinafter "Sieburth") investigates the regulation of expression of the *Arabidopsis thaliana AGAMOUS* (*AG*) endogene and compares the expression with two promoter constructs fused to the GUS reporter gene (Sieburth, see abstract; The Plant Cell, 1997, 9:355-365, copy enclosed). One construct contains the isolated promoter of the *AG* gene combined with the GUS reporter gene. The second construct contains the upstream sequences of the *AG* gene combined with intragenic sequences of the *AG* gene and the GUS reporter (Sieburth, page 356, left column). Intragenic sequences are part of the transcribed region of the respective endogene and are not present in an expression construct comprising the isolated promoter and a transgene as claimed. Sieburth discloses that the endogene and the GUS construct comprising intragenic sequences show no expression in vegetative tissue and that the expression is restricted to the reproductive tissue, whereas the expression derived from the isolated promoter is found primarily in vegetative tissue, especially leaves of transgenic *A. thaliana* (page 356-357, right column, 2nd paragraph and continuing on page 357, right column). In a later paper, the authors showed that the regulatory sequences that are responsible for these differences are located on the 2nd intron of the endogenous *AGAMAOUS* transcript (Deyholos and Sieburth, The Plant Cell, 2000,12:1799-1810, copy attached). The construct that contained the upstream sequences of the *AG* gene combined with intragenic sequences of the *AG* gene and the GUS reporter conferred the normal expression pattern of the *AG* gene. Therefore, Sieburth clearly demonstrated that the expression pattern using an isolated promoter differed from normal endogene expression (Sieburth, see, for example, abstract).

As also explained in the previous response, regulation of endogenous genes may be influenced by regulatory sequences located in the endogene transcript, such as microRNAs. For example, in Laufs *et al.* and Palatnik *et al.*, the mRNA comprises a binding site for a microRNA in the coding region of the transcript of the respective endogene. (Laufs *et al.*, Development, 2004, 131:4311-4322; Palatnik *et al.*, Nature, 2003, 425:257-263, copies attached). Such

microRNA binding sites that are endogenous to the respective promoter would not be included in expression constructs comprising an isolated promoter and a heterologous transgene. The presence of the microRNA in the respective tissue or cell leads to mRNA degradation, hence, the abundance of the respective mRNA depends not only on the regulation by the promoter but by the expression of the microRNA. The isolated promoter would therefore show a completely different specificity compared with the mRNA of the endogene in wild-type plants for this additional reason.

Therefore, conclusions regarding the specificity from the isolated promoter cannot be made based on mRNA analysis of the endogene.

As previously explained, Bown discloses that the endogenous pPP590 gene (*i.e.* the ptxA gene) in *Pisum sativum* expresses strongly in pods, but not in leaves, and weakly or not expressed in petals (Bown, page 126). As the Examiner correctly noted, this data refers only to the endogenous expression of the ptxA gene, but not the **isolated ptxA promoter** as claimed. Consistent with the findings in Sieburth, the expression pattern of the isolated promoter as claimed is different from that of the endogenous expression depicted in Bown. Therefore, the Bown reference relating to endogenous expression is not relevant to expression of the isolated promoter as clearly shown by Sieburth and the supported by the other publications mentioned above. Thus, the conclusion drawn by the Examiner from the data as presented by Bown based on endogenous expression is therefore inapplicable to the expression of the isolated promoter as claimed.

Additionally, Applicants have clearly shown through working examples that the isolated promoter claimed directs expression at least in leaf tissue but not in seed, for example, in *Arabidopsis* and in canola. Additionally, the expression in maize *in vitro* tissues and plantlets is consistent with the expression demonstrated in the dicot plants exemplified. Therefore, the specification has shown the same tissue specificity of the isolated promoter in three different plant species.

In summary, in view of the detailed description, guidance, working examples, and high level of skill, the specification enables the full scope of the present claims without undue experimentation. Additionally, even if we are to assume that the amount of experimentation to practice the full scope of the claimed invention might be extensive, as found by the Board in *Ex parte Heck*, such experimentation would have been routine, and not undue experimentation. See

Ex parte Heck, at page 12 of the attached copy. Compare, *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988) (routine screening of hybridomas was not "undue experimentation;" the involved experimentation can be considerable, so long as "routine"). On these facts, an analysis under *In re Wands* supports enablement. Analogous to the holding in *Ex parte Heck*, the specification enables the present claims and fragments and sequences with 98% identity to SEQ ID NO: 1 as claimed.

The Examiner additionally rejected claim 13 for lack of enablement. Applicants disagree. However, in order to expedite prosecution, claim 13 has been amended without prejudice or disclaimer. In light of the amendment, the rejection is rendered moot.

For at least the above reasons, reconsideration and withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 103(a)

Henkes as evidenced by Bown

Claims 1, 3, 8-15 and 22-25 are rejected under 35 USC §103(a) as being obvious over Henkes *et al.* (hereinafter "Henkes") as evidenced by Bown (GenBank Accession No. X67427, hereinafter "Bown-2"). Applicants respectfully disagree and traverse the rejection for the reasons already of record and for following additional reasons. Nonetheless, in order to expedite prosecution, the claims have been amended without disclaimer or prejudice and recite that the expression construct comprises a promoter sequence which directs expression at least in leaves but not in seed.

The examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582 (Fed. Cir. 1994).

The Examiner relies on Henkes for teaching a construct comprising a "super promoter," and identifying the ptxA promoter amongst a long list of promoters as a stress inducible promoter that can be useful for the construct taught therein. The Examiner acknowledges that Henkes does not teach the sequence of SEQ ID NO: 1, but relies on Bown-2 for such teaching. Bown-2 teaches the genomic sequence for the ptxA gene. The Examiner also acknowledges that Henkes does not teach any tissue specificity of expression. Neither Henkes nor Bown-2, alone

or in combination, teach or suggest an expression cassette which directs expression at least in leaves but not in seed. Because Henkes and Bown-2, alone or in combination, do not teach all of the claim limitations, a *prima facie* case of obviousness has not been established.

The modification suggested by the Examiner appears to be the substitution of a stress inducible promoter, the ptxA promoter, of Henkes with the genomic sequence of Bown-2 to allegedly arrive at the claimed invention.

However, the combination of familiar elements according to known methods is likely to be obvious only when it does **no more than yield predictable results**. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739-1740 (2007) ("[W]hen a patent 'simply arranges old elements with **each performing the same function it had been known to perform**' and yields no more than one would expect from such an arrangement, the combination is obvious." (citations omitted)) (emphasis added).

For the combination to be obvious, each element would need to perform the same function it had been known to perform to arrive at the claimed invention. Bown-2 discloses the genomic ptxA gene. The function of the promoter disclosed in Henkes is described as a stress inducible promoter. The Examiner's proposed modification would thus result in stress inducible expression. In contrast, the claims recite expression at least in leaves and not in seed. The expression cassette as claimed thus yields unexpected results and the elements do not perform "the same function they were known to perform" from the references cited by the Examiner. As explained MPEP § 2143, if any of the findings cannot be made (*i.e.* the substitution of one known element for another yielding predictable results to one of ordinary skill in the art), then the rationale on which the Examiner based the obviousness rejection cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. The modification or combination proposed by the Examiner does not yield predictable results and the elements cited by the Examiner do not perform the function they were known to perform. Therefore, the substitution suggested by the Examiner did not yield predictable results, but rather results contrary to expectation. Thus, since the Examiner's suggested substitution did not yield predictable results, the references cited by the Examiner do not render the claims obvious for this additional reason.

The Examiner alleges that expression in leaves is an intrinsic property of the ptxA promoter and that although Bown and Henkse do not teach this property, it would naturally flow

from their combination. The Examiner cites to the decision of *In re Baxter Travenol Labs* for this proposition. Applicants strongly disagree with the Examiner's interpretation. Please note that this decision does not mention anything about naturally flowing from a combination.

As found by the court in *In re Antonie*, which reversed the Board's finding of obviousness, it is the invention as a whole, and not some part of it, which must be obvious under 35 U.S.C.S. § 103. *In re Antonie*, 559 F.2d 618, 619-620 (CCPA 1977); see also MPEP § 2141.02 V. Furthermore, the court in *In re Antonie* found that the prior art did not reveal the property which appellant discovered and, therefore, there was no basis to find obviousness. *Id.* "Obviousness cannot be predicated on what is unknown." *See In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

Bown-2 discloses the genomic sequence of ptxA. First, nothing in Bown-2 directs one skilled in the art to the particular fragment of SEQ ID NO: 1. Furthermore, nothing in Bown-2 discloses the expression pattern claimed or an expression cassette which comprises SEQ ID NO: 1 or a promoter which directs expression in leaves and not in seed. The disclosure in Henkes only refers to a long list of potential stress inducible promoters which included ptxA citing only to the genomic sequence by GenBank Accession number. Contrary to the Examiner's assertion, the expression which would naturally flow from the combination of Henkes and Bown-2 is stress inducible expression based on the teaching of Henkes.

Alternatively, because Bown discloses that the endogenous ptxA gene expresses strongly in pods, but not in leaves and weakly or not expressed in petals as explained above, one of skill in the art could expect or predict a similar expression pattern from Bown-2 which describes the genomic sequence of the ptxA gene. Thus, contrary to the Examiner's assertion, from the teaching of Bown when referring to the ptxA gene as disclosed in Bown-2, what would naturally flow from the combination with Henkes is an expression construct which expresses strongly in pods, but not in leaves and weakly or not expressed in petals, which is inapposite to the expression of the expression construct as claimed.

Furthermore, assuming *arguendo* the references were combinable, a *prima facie* case of obviousness is rebuttable by evidence that the claimed invention possesses unexpectedly advantageous or superior properties. *In re Papesch*, 315 F.2d 382 (CCPA 1963).

Whether considering the stress inducible expression disclosed in Henkes or the expression of the ptxA gene disclosed in Bown, the expression cassette as claimed unexpectedly

directs expression of a nucleic acid sequence of interest at least in leaves but not in seed. Nothing in the references cited by the Examiner or even in the state of the art as evidenced by Bown would predict the expression cassette as claimed directing expression of a nucleic acid sequence of interest at least in leaves but not in seed as exemplified in three different plant species. To the contrary, the expression described in Bown is the opposite of the claimed expression as explained under the enablement rejection. Even if the Examiner had established that claim 1 is *prima facie* obvious over the combination of Henkes and Bown-2, this *prima facie* case would be successfully rebutted by the unexpected results achieved from the expression cassette as claimed directing expression of a nucleic acid sequence of interest at least in leaves but not in seed.

Because Henkes and Bown-2, alone or in combination, do not teach all the claim limitations, because unexpected results have been exemplified as explained above, because the substitution of one known element for another did not yield predictable results, a *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the rejection is respectfully requested for the independent claims and the claims dependent therefrom. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

Arntzen in view of Bown as evidenced by Bown-2

Claims 1, 3, 8-15 and 22-25 are further rejected under 35 USC §103(a) as being obvious over Arntzen *et al.* (hereinafter "Arntzen") in view of Bown as evidenced by Bown-2. Applicants respectfully disagree and traverse the rejection for the reasons already of record and for following additional reasons. Nonetheless, in order to expedite prosecution, the claims have been amended without disclaimer or prejudice and recite that the expression construct comprises a promoter sequence which directs expression at least in leaves but not in seed.

The explanations provided above related to Bown and Bown-2 in the enablement and obviousness rejections are equally applicable to this rejection and are incorporated herein in their entirety.

The examiner bears the initial burden of establishing *prima facie* obviousness. See *In re Rijckaert*, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). To support a *prima facie* conclusion of obviousness, the prior art must disclose or suggest all the limitations of the claimed invention. See *In re Lowry*, 32 F.3d 1579, 1582 (Fed. Cir. 1994).

The Examiner appears to base the rejection on the teaching in Bown of expression in pea pods. The Examiner alleges that because pea pods are edible, the use of the ptxA promoter to initiate transcription in an edible plant part is suggested. Applicants strongly disagree with the Examiner's characterization and conclusions.

The Examiner acknowledges that Arntzen does not teach the ptxA promoter, nor the expression in vegetative tissue without expression in seed, nor the expression of GUS. As explained above under the enablement rejection, the expression of the endogenous ptxA gene as disclosed in Bown is completely different and actually opposite to the expression of the claimed isolated promoter. Bown-2 describes the genomic sequence of the ptxA gene. Nothing in Bown-2 discloses the expression pattern claimed or an expression cassette which comprises SEQ ID NO: 1 or a promoter which directs expression in leaves and not in seed. Moreover, Bown-2 does not point to the specific fragment of SEQ ID NO: 1. Thus, Arntzen, Bown, and Bown-2, alone or in combination, do not teach or suggest an expression cassette which directs expression at least in leaves but not in seed. Because Arntzen, Bown, and Bown-2, alone or in combination, do not teach all of the claim limitations, a *prima facie* case of obviousness has not been established.

The modification suggested by the Examiner appears to be the use of the promoter taught by Bown in the invention taught by Arntzen to allegedly arrive at the claimed invention.

However, the combination of familiar elements according to known methods is likely to be obvious only when it does **no more than yield predictable results**. *KSR International Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1739-1740 (2007) ("[W]hen a patent 'simply arranges old elements with **each performing the same function it had been known to perform**' and yields no more than one would expect from such an arrangement, the combination is obvious." (citations omitted)) (emphasis added).

For the combination to be obvious, each element would need to perform the same function it had been known to perform to arrive at the claimed invention. Bown discloses that the endogenous ptxA gene expresses strongly in pods, but not in leaves and weakly or not expressed in petals as explained above. The Examiner's proposed modification would thus result in expression strongly in pods, but not in leaves and weakly or not expressed in petals. In contrast, the claims recite expression at least in leaves and not in seed. The expression cassette as claimed thus yields unexpected results and the elements do not perform "the same function

they were known to perform" from the references cited by the Examiner. As explained MPEP § 2143, if any of the findings cannot be made (*i.e.* the substitution of one known element for another yielding predictable results to one of ordinary skill in the art), then the rationale on which the Examiner based the obviousness rejection cannot be used to support a conclusion that the claim would have been obvious to one of ordinary skill in the art. The modification or combination proposed by the Examiner does not yield predictable results and the elements cited by the Examiner do not perform the function they were known to perform to arrive at the claimed invention. Therefore, the substitution suggested by the Examiner did not yield predictable results, but rather results contrary to expectation. Thus, since the Examiner's suggested substitution did not yield predictable results to arrive at the claimed invention, the references cited by the Examiner do not render the claims obvious for this additional reason.

The Examiner alleges that expression in leaves is an intrinsic property of the ptxA promoter and that although Bown does not teach this property, it would naturally flow from the combination of Arntzen and Bown. The Examiner cites to the decision of *In re Baxter Travenol Labs* for this proposition. Applicants strongly disagree with the Examiner's interpretation. Please note that this decision does not mention anything about naturally flowing from a combination.

As found by the court in *In re Antonie*, which reversed the Board's finding of obviousness, it is the invention as a whole, and not some part of it, which must be obvious under 35 U.S.C.S. § 103. *In re Antonie*, 559 F.2d 618, 619-620 (CCPA 1977); see also MPEP § 2141.02 V. Furthermore, the court in *In re Antonie* found that the prior art did not reveal the property which appellant discovered and, therefore, there was no basis to find obviousness. *Id.* "Obviousness cannot be predicated on what is unknown." *See In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993).

Bown discloses that the endogenous ptxA gene expresses strongly in pods, but not in leaves and weakly or not expressed in petals. The expression of the isolated promoter is different than that of the endogenous gene as explained above. Thus, contrary to the Examiner's assertion, from the teaching of Bown, what would naturally flow from the combination with Arntzen is expression strongly in pods, but not in leaves and weakly or not expressed in petals, which is inapposite to the expression of the expression construct as claimed.

Assuming *arguendo* the references were combinable, the combination still does not arrive at the claimed invention. The combination proposed by the Examiner would result in expression strongly in pods, but not in leaves and weakly or not expressed in petals, which is contrary to the expression cassette as now claimed which directs expression of a nucleic acid of interest at least in leaves and not in seed.

Furthermore, assuming *arguendo* the references were combinable, a *prima facie* case of obviousness is rebuttable by evidence that the claimed invention possesses unexpectedly advantageous or superior properties. *In re Papesch*, 315 F.2d 382 (CCPA 1963).

When considering the expression of the ptxA gene disclosed in Bown, the expression cassette as claimed unexpectedly directs expression of a nucleic acid sequence of interest at least in leaves but not in seed. Nothing in the references cited by the Examiner would predict the expression cassette as claimed directing expression of a nucleic acid sequence of interest at least in leaves but not in seed as exemplified in three different plant species. To the contrary, the expression described in Bown is the opposite of the claimed expression as explained under the enablement rejection. Even if the Examiner had established that claim 1 is *prima facie* obvious over the combination of Arntzen, Bown, and Bown-2, this *prima facie* case would be successfully rebutted by the unexpected results achieved from the expression cassette as claimed directing expression of a nucleic acid sequence of interest at least in leaves but not in seed.

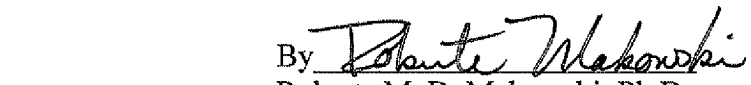
Because Arntzen, Bown, and Bown-2, alone or in combination, do not teach all the claim limitations, because unexpected results have been exemplified as explained above, because the substitution of one known element for another did not yield predictable results or the construct as claimed, a *prima facie* case of obviousness has not been established. Reconsideration and withdrawal of the rejection is respectfully requested for the independent claims and the claims dependent therefrom. *See In re Fine*, 837 F.2d 1071, 1076 (Fed. Cir. 1988) (holding that if an independent claim is nonobvious then any claim dependent therefrom is nonobvious).

CONCLUSION

For at least the above reasons, Applicants respectfully request withdrawal of the rejections and allowance of the claims. If any outstanding issues remain, the Examiner is invited to telephone the undersigned at the number given below.

Accompanying this response is a Request for Continued Examination (RCE) and a petition for a three-month extension of time to and including July 20, 2009, pursuant to 37 CFR § 1.7(a), from the filing of the Notice of Appeal dated February 19, 2009, with the required fee authorization. No further fees are believed due. However, if any additional fee is due, the director is hereby authorized to charge our deposit account no. 03-2775, under order no. 13987-00021-US from which the undersigned is authorized to draw.

Respectfully submitted,

By 

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte GREGORY R. HECK, MARIANNE MALVEN, JAMES D. MASUCCI, and JINSONG YOU

Appeal 2008-2875
Application 10/925,392
Technology Center 1600

Decided: September 16, 2008

Before DONALD E. ADAMS, LORA M. GREEN, and JEFFREY N. FREDMAN, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the Examiner's final rejection of claims 1, 3-12 and 19.[1] We have jurisdiction under 35 U.S.C. § 6(b).

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[1] This appeal was heard on August 13, 2008.

STATEMENT OF THE CASE

The "invention relates to the field of plant molecular biology and plant genetic engineering and polynucleotide molecules useful for the expression of transgenes in plants." (Spec. 1.)

The claims are directed to an isolated polynucleotide having gene regulatory activity, as well as DNA constructs containing the polynucleotide, and transgenic plants transformed with the DNA construct. Claims 1 and 3 are representative of the claims on appeal, and read as follows:

1. An isolated polynucleotide molecule having gene regulatory activity and comprising a sequence selected from the group consisting of a polynucleotide sequence comprising at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1 and a polynucleotide sequence comprising at least 98% identity to the polynucleotide sequence of SEQ ID NO: 1.

3. The isolated polynucleotide molecule according to claim 1, wherein said isolated polynucleotide molecule comprises a polynucleotide sequence which exhibits at least about 98% identity with the polynucleotide sequence of SEQ ID NO: 1.

We reverse.

ISSUE (Indefiniteness)

The Examiner contends that the phrase "at least about" renders claim 3 indefinite.

Appellants contend that the Examiner has misinterpreted the claim.

Thus, the issue on appeal is: Is the Examiner's interpretation of claim 3 correct such that the use of the phrase "at least about" renders claim 3 indefinite?

FINDINGS OF FACT

FF1 The Examiner rejects claim 3 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Appellants regard as the invention (Ans. 5).

FF2 The Examiner asserts, citing *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 1218 (Fed. Cir. 1991), that the phrase "at least about" renders the claim indefinite (Ans. 5).

PRINCIPLES OF LAW

Claims are in compliance with 35 U.S.C. § 112, second paragraph, if "the claims, read in light of the specification, reasonably apprise those skilled in the art both of the utilization and scope of the invention, and if the language is as precise as the subject matter permits." *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385 (Fed. Cir. 1987). However, "breadth is not to be equated with indefiniteness." *In re Miller*, 441 F.2d 689, 693 (CCPA 1971); *see also In re Hyatt*, 708 F.2d 712, 714-15, (Fed. Cir. 1983).

Moreover, under 35 U.S.C. § 112, third paragraph, a "claim in dependent form shall contain a reference to a claim previously set forth and then specify a further limitation of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers."

ANALYSIS

In *Amgen*, the Federal Circuit found "at least about" to be indefinite given the use of the term "about" coupled with the amount of error inherent in the assay for measurement of specific activity, as well as the fact that there was close prior art. *Amgen*, 927 F.2d at 1218. The court cautioned that the holding "should not be understood as ruling out any and all uses" of "about," as "[i]t may be acceptable in appropriate fact situations." *Id.*

Claim 3 is dependent from claim 1, and thus incorporates all of the limitations of claim 1, thus further limiting it. Claim 1 is drawn to "an isolated polynucleotide molecule" wherein the molecule is selected from the Markush group of either "a sequence selected from the group consisting of a polynucleotide sequence comprising at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1" or "a polynucleotide sequence comprising at least 98% identity to the polynucleotide sequence of SEQ ID NO: 1." As claim 3 recites that the polynucleotide molecule "comprises a polynucleotide sequence which exhibits at least about 98% identity with the polynucleotide sequence of SEQ ID NO: 1," it cannot further limit the second member of the Markush group, *i.e.*, "a polynucleotide sequence comprising at least 98% identity to the polynucleotide sequence of SEQ ID NO: 1," as it would in fact broaden the breadth of that member of the Markush group. Thus, it must modify the first member of the Markush group, that is "a sequence selected from the group consisting of a polynucleotide sequence comprising at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1." The polynucleotide molecule of claim 3 therefore must comprise at least 1000 contiguous bases of the

polynucleotide sequence of SEQ ID NO: 1 as well as being at least about 98% identical with the polynucleotide sequence of SEQ ID NO: 1 (*see also* Reply Br. 17). As sequence identity can be precisely determined, and the fact that the polynucleotide molecule of claim 3 must comprise at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1, we find that the skilled artisan would understand the meets and bounds of claim 3.

CONCLUSIONS OF LAW

Thus, we conclude that claim 3 is definite under 35 U.S.C. § 112, second paragraph, and the rejection is reversed.

ISSUE (WRITTEN DEESCRIPTION)

The Examiner contends that claims 1, 3-12, and 19 do not comply with the written description requirement of 35 U.S.C. § 112, first paragraph, as the genus encompassed by the claims is very large (Ans. 6).

Appellants contend that the Specification supports that Appellants were in possession of the full scope of the invention (App. Br. 9).

Thus, the issue on appeal is: Whether the disclosure as filed demonstrates that Appellants were in possession of the subject matter of claims 1, 3-12, and 19?

FINDINGS OF FACT

FF3 Claims 1, 3-12, and 19 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement (Ans. 6).

FF4 The Examiner finds that the "essential feature of the claimed polynucleotide is that it has 'gene regulatory activity.' However, the specification has not provided any specific structures or subsequences that are associated with this essential function." (Ans. 6.)

FF5 The Examiner finds further that the genus of sequences encompassed by the claims is very large, finding that the genus may encompass 7.7×10^{25} or larger molecule (Ans. 6-7).

FF6 Thus, according to the Examiner:

> Given the extremely large genus encompassed by the claims with only one of the species reduced to practice, and given the total lack of any description of a structure/function relationship between certain subsequences of SEQ ID NO:1 and the function of having gene regulatory activity, the requirement for written description has not been met.

(Ans. 7.)

PRINCIPLES OF LAW

"The burden of showing that the claimed invention is not described in the application rests on the PTO in the first instance." *In re Edwards*, 568 F.2d 1349, 1354 (CCPA 1978). A written description of an invention involving a nucleic acid, like a description of a chemical genus, "requires a precise definition, such as by structure, formula, [or] chemical name," of the claimed subject matter sufficient to distinguish it from other materials. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993). While "examples explicitly covering the full scope of the claim language" are not typically required, a sufficient number of representative species must be included "to demonstrate that the [applicants] possesses the full scope of the invention." *LizardTech,*

Inc. v. Earth Resource Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005). However,

> the determination of what is needed to support generic claims to biological subject matter depends on a variety of factors, such as the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, the predictability of the aspect at issue, and other considerations appropriate to the subject matter.

Capon v. Eshhar, 418 F.3d 1349, 1359 (Fed. Cir. 2005).

ANALYSIS

Appellants argue that they "have explicitly taught the structure of the promoter sequences by providing the nucleic acid sequence of SEQ ID NO:1, a sequence provided with the application as filed." (App. Br. 10.) According to Appellants, "[w]hile the claims encompass fragments of the sequence SEQ ID NO:1 and sequences with at least . . . 98% identity with SEQ ID NO:1, these groups define a subset of sequences fully described by SEQ ID NO:1." (*Id.*)

We agree. Claim 1, the broadest claim on Appeal, recites an "isolated polynucleotide molecule having gene regulatory activity and comprising a sequence selected from the group consisting of a polynucleotide sequence comprising at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1 and a polynucleotide sequence comprising at least 98% identity to the polynucleotide sequence of SEQ ID NO: 1." As to "a polynucleotide sequence comprising at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1," structure is provided, *i.e.*, 1000 contiguous bases of SEQ ID NO: 1, a sequence that is 2190 nucleotides

long, and also knows the function, promoter activity. As to sequences that have "at least 98% identity to the polynucleotide sequence of SEQ ID NO: 1," the same analysis applies, that is, the skilled artisan would know the structure, i.e. at least 98% identity to SEQ ID NO: 1, as well as the function, having promoter activity.

CONCLUSION

Thus, we find that claims 1, 3-12, and 19 comply with the written description requirement of 35 U.S.C. § 112, first paragraph, and the rejection is reversed.

ISSUE (ENABLEMENT)

The Examiner contends that the Specification fails to enable claims 1, 3-12, and 19 as required by 35 U.S.C. § 112, first paragraph.

Appellants contend that the claims are enabled by the Specification (App. Br. 14).

Thus, the issue on Appeal is: does the Specification enable claims 1, 3-12, and 19 as required by 35 U.S.C. § 112, first paragraph?

FINDINGS OF FACT

FF7 The Examiner rejected claims 1, 3-12, and 19 under 35 U.S.C. § 112, first paragraph, on the grounds that "the specification, while being enabling for an isolated polynucleotide molecule comprising SEQ ID NO: 1 and for polynucleotides comprising at least 1000 contiguous bases of SEQ ID NO:1, does not reasonably provide enablement for an isolated polynucleotide

molecule comprising a sequence which has at least 98% identity, at least about 98% identity, or at least 99% identity with SEQ ID NO:1." (Ans. 7-8.)

FF8 The Examiner made the following findings with respect to the factors set out in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).[2]

FF9 *The breadth of the claims*: The Examiner notes that claims "1, 3, and 19 are broadly drawn to an isolated polynucleotide molecule having gene regulatory activity and having at least 98% identity, or at least about 98% identity, or at least 99% identity with SEQ ID NO:1." (Ans. 8.)

FF10 *Nature of the invention and the state of the prior art*: The Examiner notes that the "nature of the invention is the construction of a chimeric promoter for use in plants." (Ans. 8.)

FF11 *The amount of direction or guidance presented and the existence of working examples*: According to the Examiner while the Specification teaches that a chimeric promoter, presumably SEQ ID NO:1, was cloned into two different expression vectors to drive expression of two different marker genes, it "has not taught any polynucleotides with 98% identity or 'about' 98% identity or 99% identity to SEQ ID NO:1 that have gene regulatory activity." (Ans. 8-9.)

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[2] The factual considerations discussed in *Wands* are: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

FF12 *The relative skill of those in the art, the predictability or unpredictability of the art, and the quantity of experimentation necessary*: The Examiner, citing Donald[3] and Kim,[4] states that the prior art demonstrates "that mutation of promoter sequences produces unpredictable results," and that "[e]ven minor alterations can alter promoter activity." (Ans. 9.)

PRINCIPLES OF LAW

"When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application." *In re Wright*, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).

"[T]o be enabling, the specification . . . must teach those skilled in the art how to make and use *the full scope of the claimed invention* without 'undue experimentation.'" *Id.* at 1561, (emphasis added), *quoted in Genentech, Inc. v. Novo Nordisk A/S,* 108 F.3d 1361, 1365 (Fed. Cir. 1997). Thus, "there must be sufficient disclosure, either through illustrative examples or terminology, to teach those of ordinary skill how to make and

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[3] Donald, "Mutation of either G box or I box sequences profoundly affects expression from the Arabidopsis rbcS-1a promoter," *The EMBO J.*, Vol. 9, pp. 1717-1726 (1990).

[4] Kim, "A 20 nucleotide upstream element is essential for the nopaline synthase (*nos*) promoter activity," *Plant Molecular Biology*, Vol. 24, pp. 105-117 (1994).

use the invention as broadly as it is claimed." *In re Vaeck*, 947 F.2d 488, 496 & n. 23 (Fed. Cir. 1991), *quoted in Enzo Biochem, Inc. v. Calgene, Inc.*, 188 F.3d 1362, 1374 (Fed. Cir. 1999). Some experimentation, even a considerable amount, is not "undue" if, e.g., it is merely routine, or if the specification provides a reasonable amount of guidance as to the direction in which the experimentation should proceed. *See In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988).

ANALYSIS

The Examiner concludes:

> In the absence of this guidance, one skilled in the art is left to randomly produce an endless number of substitutions or deletions of nucleotides from SEQ ID NO:1, and test each new molecule for having gene regulatory activity, which is undue experimentation. Given the breadth of the claims encompassing any polynucleotide have 98% identity, "about" 98% identity, or 99% identity to SEQ ID NO:1, and given unpredictability of the art and lack of guidance of the specification as discussed above, undue experimentation would have been required by one skilled in the art to make and use the claimed invention.

(Ans. 9.)

Appellants argue that it is well within the level of ordinary skill in the art to prepare nucleic acid sequences that are 98% identical to SEQ ID NO: 1 (App. Br. 15). Moreover, the Specification teaches the preparation of derivatives of full length promoter sequences, as well as methods of determining the activity of such promoter sequences (*id.*). As to Kim and Donald, while Appellants acknowledge that the "some deletions and mutations will reduce activity of a promoter," both references "employ

standard screening methods to assess the promoter activity of sequences comprising deletions and/or point mutations." (App. Br. 18-19.)

We agree. Even if we were to assume that the amount of experimentation to practice the full scope of the claimed invention might be extensive, such experimentation would have been routine. The art cited by the Examiner demonstrates the routine nature of promoter analysis, since both Donald and Kim use standard methods to determine which sequence elements affect promoter strength and which elements have no impact. The methods for performing such screening were provided by the Specification, and were also well known to those skilled in the art. *See, e.g., Johns Hopkins Univ. v. Cellpro, Inc.*, 152 F.3d 1342, 1360 (Fed. Cir. 1998) ("test [for undue experimentation] is not merely quantitative ... if it is merely routine"); *Ex parte Kubin*, 83 USPQ2d 1410, 1416 (Bd. Pat. App. & Int. 2007). Thus, we conclude the Specification provides an enabling disclosure.

CONCLUSIONS OF LAW

We thus conclude that the Specification enables claims 1, 3-12, and 19 as required by 35 U.S.C. § 112, first paragraph, and the rejection is reversed.

ISSUE (Anticipation)

The Examiner contends that polynucleotide molecule of claim 3 is anticipated by Brevario.[5]

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[5] Breviaro, GenBank Accession AJ488063 (2002).

Appellants contend that "because claim 3 is more narrow than claim 1 and claim 1 is acknowledged to define over the art, the rejection is without merit." (Reply Br. 17.)

Therefore, the issue on appeal is: Has the Examiner established that the polynucleotide molecule of claim 3 is anticipated by the sequence of Brevario?

FINDINGS OF FACT

FF13 Claim 3 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Brevario.

FF14 Claim 3 is dependent from claim 1, but claim 1 was not rejected.

FF15 Brevario is cited for teaching a sequence of a partial tubA2 gene that comprises 93.8% identity with SEQ ID NO: 1 (Ans. 10).

PRINCIPLES OF LAW

In order for a prior art reference to serve as an anticipatory reference, it must disclose every limitation of the claimed invention, either explicitly or inherently. *In re Schreiber*, 128 F.3d 1473, 1477 (Fed. Cir. 1997).

ANALYSIS

As noted above in the indefiniteness analysis, the polynucleotide molecule of claim 3 must comprise at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1 as well as being at least about 98% identical with the polynucleotide sequence of SEQ ID NO: 1. As the Examiner has not made any findings that the sequence of Brevario

comprises comprise at least 1000 contiguous bases of the polynucleotide sequence of SEQ ID NO: 1, and apparently does not do so as claim 1 was not included in the rejection, the Examiner has not established that the sequence of Brevario meets all of the limitations of claim 3, and thus has not set forth a prima facie case that Brevario anticipates claim 3.

CONCLUSION

We therefore find that the Examiner has failed to establish that the polynucleotide molecule of claim 3 is anticipated by the sequence of Brevario, and the rejection is reversed.

SUMMARY

Because the Examiner has failed to set forth a prima facie case of patentability as to any of the claims on appeal, all of the rejections on appeal are reversed.

REVERSED

Ssc:

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